Determination of Leak and Respiratory Airflow

Field of the Invention

5   The invention relates to methods and apparatus for the determination of leakage airflow and true respiratory airflow, particularly during mechanical ventilation.

The airflow determination can be for a subject who is either spontaneously or non-spontaneously breathing, or moves between these breathing states. The invention is 10 especially suitable for, but not limited to, normally conscious and spontaneously breathing human subjects requiring long term ventilatory assistance, particularly during sleep.

Background of the Invention

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In this specification any reference to a "mask" is to be understood as including all forms of devices for passing breathable gas to a person's airway, including nose masks, nose and mouth masks, nasal prongs/pillows and endotracheal or tracheostomy tubes.

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During mechanical ventilation, breathable gas is supplied for example via a mask, at a pressure which is higher during inspiration and lower during expiration. It is useful to measure the subject's respiratory airflow during mechanical ventilation to assess adequacy of treatment, or to control the operation of the ventilator.

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Respiratory airflow is commonly measured with a pneumotachograph placed in the gas delivery path between the mask and the ventilator. Leaks between the mask and the subject are unavoidable. The pneumotachograph measures the sum of the respiratory airflow plus the flow through the leak. If the instantaneous flow through the 30 leak is known, the respiratory airflow can be calculated by subtracting the flow through the leak from the flow at the pneumotach.

Known methods to correct for the flow through the leak assume (i) that the leak is substantially constant, and (ii) that over a sufficiently long time, inspiratory and 35 expiratory respiratory airflow will cancel. If these assumptions are met, the average flow through the pneumotach over a sufficiently long period will equal the magnitude of the leak, and the true respiratory airflow may then be calculated as described.

The known method is only correct if the pressure at the mask is constant. If the mask pressure varies with time (for example, in the case of a ventilator), assumption (i) above will be invalid, and the calculated respiratory airflow will therefore be incorrect. This is shown markedly in Figs. 1a-1f.

Fig. 1a shows a trace of measured mask pressure in bi-level CPAP treatment between about 4 cm H_2O on expiration and 12 cm H_2O on inspiration. Fig. 1b shows a trace of true respiratory airflow in synchronism with the mask pressures. At time = 21 seconds a mask leak occurs, resulting in a leakage flow from the leak that is a function of the treatment pressure, as shown in Fig. 1c. The measured mask flow shown in Fig. 1d now includes an offset due to the leak flow. The prior art method then determines the calculated leak flow over a number of breaths, as shown in Fig. 1e. The resulting calculated respiratory flow, as the measured flow minus the calculating leak flow is shown in Fig. 1f, having returned to the correct mean value, however is incorrectly scaled in magnitude, giving a false indication of peak positive and negative airflow.

Another prior art arrangement is disclosed in European Publication No. 0 714 670 A2, including a calculation of a pressure-dependent leak component. The methodology relies on knowing precisely the occurrence of the start of an inspiratory event and the start of the next inspiratory event. In other words, the leak calculation is formed as an average over a known breath and applied to a subsequent breath.

This method cannot be used if the moment of start and end of the previous breath are unknown. In general, it can be difficult to accurately calculate the time of start of a breath. This is particularly the case immediately following a sudden change in the leak.

Furthermore, the method will not work in the case of a subject who is making no respiratory efforts, and is momentarily not being ventilated at all, for example during an apnea, because for the duration of the apnea there is no start or end of breath over which to make a calculation.

The present invention seeks to provide a determination of leak flow and true respiratory airflow, accounting for the variations in flow through a leak as a function of pressure.

Summary of the Invention

The invention discloses a method for determining instantaneous leak flow at a mask having a leak path during mechanical ventilation, the method comprising the steps of:

    (a)   determining instantaneous airflow at the mask;

    (b)   determining instantaneous pressure at the mask;

    (c)   estimating non-linear conductance of said leak path as the low-pass filtered instantaneous airflow divided by the low-pass filtered square root of the instantaneous pressure; and

    (d)   determining said instantaneous leak flow to be said conductance multiplied by the square root of the said instantaneous pressure.

The invention further discloses a method for determining instantaneous respiratory airflow for a subject receiving breathable gas by a mask and in the presence of any mask leak, the method comprising the steps of:

    (a)   determining instantaneous airflow at the mask;

    (b)   determining instantaneous pressure at the mask;

    (c)   estimating non-linear conductance of said leak path as the low pass filtered instantaneous airflow divided by the low pass filtered square root of the instantaneous pressure;

    (d)   determining instantaneous leak flow to be said conductance multiplied by the square root of the said instantaneous pressure; and

    (e)   calculating the respiratory airflow as the instantaneous airflow minus the instantaneous leak flow.

The invention yet further discloses apparatus for determining respiratory airflow for a subject receiving breathable gas by a mask and in the presence of any mask leak, the apparatus comprising:

    transducer means located at or proximate the mask to determine instantaneous mask airflow and pressure; and

    processing means for estimating non-linear conductance of said leak path as the low pass filtered instantaneous airflow divided by the low pass filtered square root of the instantaneous pressure, determining instantaneous leak flow to be said conductance multiplied by the square root of the said instantaneous pressure, and calculating the respiratory airflow as the instantaneous airflow minus the instantaneous leak flow.

The invention yet further discloses apparatus for providing continuous positive airway pressure treatment or mechanical ventilation, the apparatus comprising:

a turbine for the generation of a supply of breathable gas;

a gas delivery tube having connection with the turbine;

a mask having connection to the delivery tube to supply said breathable gas to a subject's airway;

transducer means located at or proximate the mask to determine instantaneous mask airflow and pressure;

processor means for estimating non-linear conductance of said leak path as the low pass filtered instantaneous airflow divided by the low pass filtered square root of the instantaneous pressure, determining instantaneous leak flow to be said conductance multiplied by the square root of the said instantaneous pressure, and calculating the respiratory airflow as the instantaneous airflow minus the instantaneous leak flow; and

control means to control the flow generator to, in turn, control the mask pressure and/or mask airflow on the basis of the calculated respiratory airflow.

The invention yet further discloses a computer program for executing the steps referred to above.

In one preferred form, time constants of the low pass filtering are dynamically adjusted dependent upon sudden changes in the instantaneous leak flow.

Embodiments of the invention provide advantages over the prior art. There is no need to know when transitions between respiratory phases occurs. The independence from knowledge of the subject's respiratory state has the important result that the leak flow calculation is accurate in apneic (i.e. no flow) instances on the part of the subject or the mechanical ventilator.

Brief Description of the Drawings

Embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figs. 1a-1f shows traces of pressure and airflow from which respiratory airflow is calculated in accordance with a prior art method:

Figs. 2a and b show schematic diagrams of two embodiments of ventilatory assistance apparatus;

Fig. 3 is a block flow diagram of a method for determining instantaneous respiratory airflow; and

Fig. 4 shows traces of pressure, airflow and other variables from which respiratory airflow is calculated;

Fig. 5 shows a schematic diagram of ventilatory assistance apparatus of another embodiment;

Fig. 6 shows a fuzzy membership function for the calculation of the extent A_I to which the time t_{ZI} since the most recent positive going zero crossing of the calculated respiratory airflow is longer than the expected time T_I;

Fig. 7 shows a fuzzy membership function for the calculation of the extent B_I to which the calculated inspiratory respiratory airflow f_{RESP} is large positive;

Fig. 8 shows a fuzzy membership function for the calculation of the extent A_E to which the time t_{ZE} since the most recent negative going zero crossing in the calculated respiratory airflow is longer than the expected time T_E;

Fig. 9 shows a fuzzy membership function for the calculation of the extent B_E to which the respiratory airflow f_{RESP} is large negative; and

Fig. 10 shows the relation between an index J and time constant τ.

Detailed Description of Preferred Embodiments

Fig. 2a shows mechanical ventilation apparatus 10 embodying the invention.

The subject/patient wears a nose mask 12 of any known type. The subject equally could wear a face mask or nasal prongs/pillows, or alternatively have an endotracheal tube or tracheostomy tube in place. A turbine/blower 14, operated by a mechanically coupled electrical motor 16, receives air or breathable gas at an inlet 18 thereof, and supplies the breathable gas at a delivery pressure to a delivery tube/hose 20 having connection at the other end thereof with the nose mask 12. Breathable gas thus is provided to the subject's airway for the purpose of providing assisted respiration, with the subject's expired breath passing to atmosphere by an exhaust 22 in the delivery tube 20, typically located proximate to the mask 12.

A pneumotachograph 24 is placed in the delivery tube 20 between the mask 12 and the exhaust 22 to provide two pressure signals, P_2 and P_1, across the pneumotachograph, each passed by hoses 28,30 to a differential pressure sensor 32. A determination of the flow of gas in the mask 12 is made the differential pressure, P_2-P_1, resulting in a flow signal f_d. The mask pressure, P_2, also is passed to a pressure sensor 34 by a tapped line 36 taken from the respective hose 28, to generate a delivery pressure signal, p_m, output from the pressure sensor 34.

Both the flow signal, f_d, and the pressure signal, p_m, are passed to a microcontroller 38 where they are sampled for subsequent signal processing, typically at a rate of 50 Hz.

The microcontroller 38 is programmed to process the flow and pressure signals (f_d, P_m) to produce an output control signal, y_o, provided to an electronic motor servo-controller 42 that, in turn, produces a motor speed control output signal, v_o. This signal is provided to the motor 16 to control the rotational speed of the turbine 14 and provide the desired treatment pressure, P_2, at the nose mask 12.

The motor servo-controller 42 employs a negative feedback control technique that compares the actual delivery pressure, in the form of the signal p_m, with the control signal y_o. For convenience, this control stratagem may be independent of operation of the microcontroller 38.

Operation of the controlling of the microcontroller 38, so far as a calculation of respiratory airflow is concerned, broadly is as follows. In a sampled manner, the conductance of any mask leak is calculated, then the instantaneous flow through the leak is calculated. The flow through the leak is subtracted from the total mask flow to calculate the true instantaneous respiratory airflow.

Fig. 2b shows an alternative embodiment of a system for determining true respiratory airflow during mechanical ventilation. The mechanical ventilation system 10' of Fig. 1b differs from that of Fig. 1a firstly in that the microcontroller 38 plays no part in control of the ventilator 50, rather only receives and data processes the electrically transduced mask pressure and flow signals p_m, f_d to determine and generate the instantaneous respiratory flow f_{RESP}. The ventilator 50 has an internal drive signal provided by an oscillator 44. The motor servo controller also may or may not receive the mask pressure signal p_m as a form of feedback control. Indeed, the ventilator 50 can be realised by any convenient form of known generic ventilation device.

The controlling software resident within the microcontroller 38 performs the following steps in determining the respiratory airflow as broadly described above, as also shown in the flow diagram of Fig. 3.

The word "average" is used herein in the most general sense of the result of a low pass filtering step, and is not confined to an arithmetic mean.

1. Repeatedly sample the mask airflow f_d to give a sampled signal f_{MASK}, and the mask pressure P_m to give a sampled signal P_{MASK}, for example at intervals of $T = 20$ milliseconds. (Steps 50,52).

2. Calculate the average leak, LP(L), as being the result of low pass filtering the airflow, f_{MASK}, with a time constant of 10 seconds. (Step 54).

3. Calculate the average of the square root of the mask pressure, $LP(\sqrt{P}_{MASK})$, as being the result of low pass filtering the square root of the mask pressure, P_{MASK}, with a time constant of 10 seconds. (Step 56).

4. Calculate the conductance, G, of any leak (Step 58), from the equation:

$$G = LP(L) / LP(\sqrt{P}_{MASK})$$

5. Calculate the instantaneous leak flow, f_{LEAK}, through the leak (Step 60), from the equation:

$$f_{LEAK} = G\sqrt{P_{MASK}}$$

If there is no leak flow, the value of LP(L) will be equal to zero, as will G and hence f_{LEAK}. Thus the methodology is valid also where leak is equal to zero - no leak.

At this juncture the leak flow has been determined, such as would be desired for a leak flow detector. If desired, the instantaneous respiratory airflow can be subsequently determined by the following step.

6. Calculate the instantaneous respiratory airflow, f_{RESP}, by subtracting the instantaneous leak from the mask flow (Step 62):

$$f_{RESP} = f_{MASK} - f_{LEAK}$$

Figs. 4a-4h illustrate the methodology of the embodiment described above with reference to Fig. 2b. At time, t = 21 sec, a continuing leak of approximately 1 l/sec is introduced. Fig. 4e shows the mean mask flow. Fig. 4f represents the calculated conductance G, from which the mask leak flow can be estimated as shown in Fig. 4g. Finally, Fig. 4h shows how the calculated respiratory airflow recovers within approximately 30 seconds, and, importantly, gives the correctly scaled (true) magnitude of airflow.

With regard to setting the instantaneous output signal y_0, the microcontroller broadly executes the following steps:

7. If the calculated true respiratory airflow f_{RESP} is above a threshold, for example 0.05 L/sec, y_0 is set to a value corresponding to an inspiratory pressure, P_{INSP}. Otherwise y_0 is set to a value corresponding to an expiratory pressure, P_{EXP}. In general, P_{INSP} is higher than P_{EXP}, but in the case of continuous positive airways pressure, P_{EXP} may be equal to P_{INSP}. (Step 66).

It is to be understood that many other methods of determining y_0 from f_{MASK} may be used in step 7, for example as described in the text *Principles and Practice of Mechanical Ventilation*, edited by Martin J. Tobin (McGraw Hill Inc, 1994).

In order to control ventilation, it is necessary to measure the subject's ventilation. In the presence of a leak, the ventilation delivered by the assisted ventilation apparatus is greater than the ventilation delivered to the subject. Known devices which servo-control ventilation cope with this by collecting the exhaled air stream with a complex system of valves, and then measuring the exhaled ventilation. This is inappropriate for devices for use in a domestic setting during sleep, because of the attendant weight, complexity, and expense. The embodiment described compensates for the leak by continuously measuring the nonlinear conductance of the leak, and allowing for the instantaneous flow through the leak as a function of pressure.

Fig. 5 shows an alternate arrangement for ventilatory assistance apparatus 10' embodying the invention. In this arrangement, the pneumotachograph 24' is interposed between the turbine 14 and the delivery hose 20.

This arrangement removes the pressure sensing hoses and pneumotachograph from the region of the mask 12. The pressure at the mask, P_{MASK}, is calculated from the delivery pressure at the turbine 14, and from the pressure drop down the air delivery hose 20, which for any particular delivery hose is a known function of the flow at the pneumotachograph 24. Further, the microcontroller 38 must also calculate the flow through the mask from the flow at the turbine 14 less the flow through the exhaust 22, which for any particular exhaust is a known function of the pressure at the mask 12.

In more detail, this involves the steps of, firstly measuring the pressure p3 at the turbine 14 with the pressure sensor 34 to produce an electrical signal p_t. Next the differential pressure p4-p3 is measured across the pneumotachograph 24' by the differential pressure sensor 32 to produce an electrical signal f_t. In a sampled manner, p_t and f_t are digitized to yield the sampled turbine pressure and flow signals $P_{TURBINE}$ and $F_{TURBINE}$.

The pressure at the mask P_{MASK} and the sampled airflow at the mask f_{MASK} 12 are calculated from the turbine pressure $P_{TURBINE}$ and the flow at the outlet of the turbine $F_{TURBINE}$ as follows:

1. Calculate the pressure drop ΔP_{TUBE} down the air delivery tube 20, from the flow at the outlet of the turbine $F_{TURBINE}$:

$$\Delta P_{TUBE} = \text{sign}(F_{TURBINE}) \times K_1 (F_{TURBINE})^2 + K_2 F_{TURBINE}$$

where K_1 and K_2 are empirically determined constants, and sign (x) is 1 for $x \geq 0$ and -1 otherwise.

2. Calculate the pressure at the mask, P_{MASK}, as the pressure at the turbine $P_{TURBINE}$ less the pressure drop ΔP_{TUBE} down the air delivery tube 20:

$$P_{MASK} = P_{TURBINE} - \Delta P_{TUBE}.$$

3. Calculate the flow, $f_{EXHAUST}$, through the exhaust 22, from the pressure at the mask P_{MASK}:

$$f_{EXHAUST} = \text{sign}(P_{MASK}) \times K_3 \sqrt{\text{abs}(P_{MASK})}$$

where K_3 is determined empirically.

4. Calculate the flow, f_{MASK}, into the mask 12 as the flow at the turbine 14 less the flow through the exhaust 22:

$$f_{MASK} = f_{TURBINE} - f_{EXHAUST}.$$

The foregoing embodiments describe low-pass filtering of both the instantaneous airflow and the square root of the instantaneous pressure with a time constant t of 10 seconds. This time constant, τ, can be advantageously dynamically adjustable.

If the conductance of the leak suddenly changes, then the calculated conductance will initially be incorrect, and will gradually approach the correct value at a rate which will be slow if the time constant of the low pass filters is long, and fast if the time constant is short. Conversely, if the impedance of the leak is steady, the longer the time constant the more accurate the calculation of the instantaneous leak.

Therefore, it is desirable to lengthen the time constant if it is certain that the leak is steady, reduce the time constant if it is certain that the leak has suddenly changed, and to use intermediately longer or shorter time constants if it is intermediately certain that the leak is steady.

If there is a large and sudden increase in the conductance of the leak, then the calculated respiratory airflow will be incorrect. In particular during apparent inspiration, the calculated respiratory airflow will be large positive for a time that is large compared with the expected duration of a normal inspiration. Conversely, if there is a sudden decrease in conductance of the leak, then during apparent expiration the calculated respiratory airflow will be large negative for a time that is large compared with the duration of normal expiration.

Therefore, an index of the degree of certainty that the leak has suddenly changed is derived, such that the longer the airflow has been away from zero, and by a larger amount, the larger the index; and the time constant for the low pass filters is adjusted to vary inversely with the index. In operation, if there is a sudden and large change in the leak, the index will be large, and the time constant for the calculation of the conductance of the leak will be small, allowing rapid convergence on the new value of the leakage conductance. Conversely, if the leak is steady for a long time, the index will be small, and the time constant for calculation of the leakage conductance will be large, enabling accurate calculation of the instantaneous respiratory airflow. In the spectrum of intermediate situations, where the calculated instantaneous respiratory airflow is larger and for longer periods, the index will be progressively larger, and the time constant for the calculation of the leak will progressively reduce. For example, at a moment in time where it is uncertain whether the leak is in fact constant, and the subject merely commenced a large sigh, or whether in fact there has been a sudden increase in the leak, the index will be of an intermediate value, and the time constant for calculation of the impedance of the leak will also be of an intermediate value. One advantage is that some corrective action will occur very early.

Another advantage is that there is never a moment where the leak correction algorithm is "out of control" and needs to be restarted, as described for prior art European Patent Publication No. 0 714 670 A2.

In a preferred embodiment, the above index is derived using fuzzy logic. The fuzzy extent A_l to which the airflow has been positive for longer than expected is calculated from the time t_{zl} since the last positive-going zero crossing of the calculated respiratory airflow signal, and the expected duration T_B of a normal inspiration for the

particular subject, using the fuzzy membership function shown in Fig. 6. The fuzzy extent B_I to which the airflow is large and positive is calculated from the instantaneous respiratory airflow using the fuzzy membership function shown in Fig. 7. The instantaneous index I_I of the degree of certainty that the leak has suddenly increased is calculated as the fuzzy intersection (lesser) of A_I and B_I.

Comparable calculations are performed for expiration as follows. The fuzzy extent A_E to which the airflow has been negative for longer than expected is calculated from the time t_{ZE} since the last negative-going zero crossing of the calculated respiratory airflow signal, and T_E, the expected duration of a typical expiration for the particular subject, using the membership function shown in Fig. 8. The fuzzy extent B_E to which the airflow is large negative is calculated from the instantaneous respiratory airflow using the fuzzy membership function shown in Fig. ·9. The instantaneous index I_E of the degree of certainty that the leak has suddenly decreased is calculated as the fuzzy intersection of A_E and B_E.

The instantaneous index I of the extent to which there has been a sudden change in the leak (either an increase or a decrease) is calculated as the fuzzy union (larger) of indices I_I and I_E. The instantaneous index I is then passed through a peak detector followed by a low pass filter with a time constant of, for example 2 seconds, to yield the desired index J. Thus if index I becomes momentarily large, index J will be initially large and remain so for a few seconds. The time constant τ for the low pass filters used in the calculation of the conductance of the leak is then adjusted to vary inversely with the index J, as shown in Fig. 10. For example, if the expected duration of a normal respiratory cycle were 4 seconds the time constant is set to 10 seconds if the index J is zero, (corresponding to complete certainty that the leak is steady), and to 1 second if the index J is unity (corresponding to complete certainty that the leak is suddenly changing), and to intermediate values for intermediate cases.

The embodiments described refer to apparatus for the provision of ventilatory assistance, however, it is to be understood that the invention is applicable to all forms of mechanical ventilation and apparatus for the provision of continuous positive airway pressure treatment. The apparatus can be for the provision of a constant treatment pressure, multi-level (IPAP and EPAP) treatment or autosetting (adjusting) treatment or other forms of mechanical ventilation, including Proportional Assist Ventilation (PAV) as taught by M Younes in the above-noted text.

The methodology described can be implemented in the form of a computer program that is executed by the microcontroller described, or by discrete combinational logic elements, or by analog hardware.